

PCT

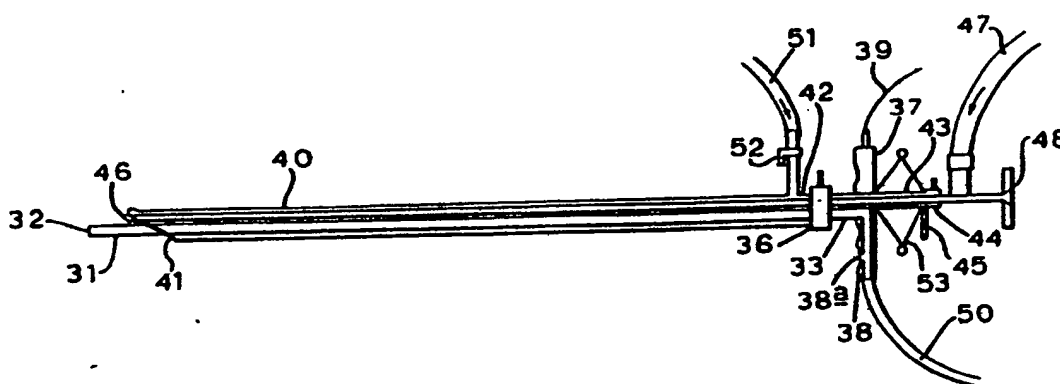
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61B 17/39	A1	(11) International Publication Number: WO 90/03152 (43) International Publication Date: 5 April 1990 (05.04.90)
(21) International Application Number: PCT/GB89/01124 (22) International Filing Date: 25 September 1989 (25.09.89) (30) Priority data: 8822492.8 24 September 1988 (24.09.88) GB (71)(72) Applicants and Inventors: CONSIDINE, John [GB/GB]; 8 Reddings Road, Moseley, Birmingham B13 8LN (GB). COLIN, John, Bunce [GB/GB]; 49 Elderpark Gardens, Govan, Glasgow G51 3NX (GB). (74) Agent: ATTIFIELD, Donald, J.; Brookes, Martin & Wilson, Prudential Buildings, 5 St. Philip's Place, Birmingham B3 2AF (GB).	(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), SE (European patent), US. Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

BEST AVAILABLE COPY

(54) Title: ELECTRO-SURGICAL APPARATUS FOR REMOVING TUMOURS FROM HOLLOW ORGANS OF THE BODY



(57) Abstract

Disclosed is an endoscope for use in the removal of tumours from hollow body organs such as the bladder. The endoscope consists of sheath (49) through which extends a telescope (46) and a suction diathermy tube (31) the non-operation end (33) of which communicates with a suction device. Provision (51, 52) is made for an irrigation fluid to be passed through the endoscope. The diathermy tube (31) may be a flexible plastics tube (2, 61) and the diathermy electrode tip (7, 8) may be formed from electrically conducting resistance wire connected (5, 39, 63) to a diathermy machine. The electrode tip is found adjacent an aperture (41) at the operative of the tube whereby tissue can be immediately removed by suction after severance by the electrode tip. The degree of suction applied to tube (31) being controlled by a finger hole (38a) located at or near the end (33) of the tube (31). Alternatively the tube (31) may be formed of a metal tube (34) coated with an insulating plastics material (35) and having a cutting or coagulating tip (34a), provision (37, 38, 43, 45, 53, 54) being made for reciprocating the tube up and down the endoscope.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MR	Mauritania
BE	Belgium	GA	Gabon	MW	Malawi
BF	Burkina Faso	GB	United Kingdom	NL	Netherlands
BG	Bulgaria	HU	Hungary	NO	Norway
BJ	Benin	IT	Italy	RO	Romania
BR	Brazil	JP	Japan	SD	Sudan
CA	Canada	KP	Democratic People's Republic of Korea	SE	Sweden
CF	Central African Republic	KR	Republic of Korea	SN	Senegal
CG	Congo	LI	Liechtenstein	SU	Soviet Union
CH	Switzerland	LK	Sri Lanka	TD	Chad
CM	Cameroon	LU	Luxembourg	TG	Togo
DE	Germany, Federal Republic of	MC	Monaco	US	United States of America
DK	Denmark				

WO 90/03152

PCT/GB89/01124

1

Electro-surgical apparatus for removing tumours from hollow organs of the body

The present invention relates to an apparatus for the removal of tumours from hollow body organs accessible to an endoscope, and in particular the removal of tumours from the bladder.

5 The removal of tumours from hollow organs of the body by surgery frequently results in the release of viable free tumour cells which may gain attachment to the mucosa thereby resulting in the reoccurrence of tumours.

10 Removal of tumours from the bladder is generally achieved either by an open operation (supra-pubic diathermy excision) or by transurethral resection (TURO). It has been suggested by Smith [J.R.S.H. 74 547 to 550 (1981)], among others, that the

15 implantation of free tumour cells may be enhanced by instrumental damage to the mucosa during the evacuation of tumour fragments by TUR. To overcome this problem intravesical installations of cytotoxic drugs have been examined [Zinck et al Journal of
20 Urology 134 1110-1114 (1985)]. In open surgery it is

usual for friable superficial portions of the tumour to be removed via a suction tube inserted through the first opening made in the bladder wall before the normal tissues are exposed to contamination. The application of this technique to TUR is expected to reduce the rate of recurrence of tumours resulting from TUR resection.

We therefore provide an apparatus for use in the removal of tumours from hollow body organs accessible to an endoscope comprising, in combination, an endoscope, having a closed end through which the telescope passes and an open operative end, a diathermy suction tube extending through the closed end of the said endoscope to the open end and having an exposed electrode tip portion adjacent to an opening in or at the operative end of the tube, the said electrode being connected to a source of electrical power.

The said opening in the tubing may be formed at the end of the tube i.e., the tube may be open-ended, or in a sidewall adjacent to the end thereof. Additional small openings in the tube sidewall may also be provided if required.

WO 90/03152

PCT/GB89/01124

3

In one form the diathermy tube is formed from flexible translucent plastics material and the said diathermy electrode tip is formed of electrically conductive resistance wire connected to the source of electrical power by at least one electrically conductive wire located in the wall of the said tube.

The diathermy electrode wires are preferably embedded in the wall of the tubing but may, also, for example be secured along an outside wall.

It is preferred that the electrode is connected to two wires passing along diametrically opposed portions of the tubing wall.

The exposed tip of the electrode may be formed in any convenient shape, for example it may be a wire having a circular or semi-circular shape preferably of the same diameter as the internal diameter of the opening in the tubing. The wire may be in contact with the wall of the opening or spaced therefrom and may be parallel or at an angle to the face of the opening.

In one form the diathermy tube is formed from an electrically conductive metallic tube coated with an insulating material, the operative tip portion of tube being left bare to provide a diathermy

WO 90/03152

PCT/GB89/01124

4

electrode, the said tip portion extending beyond the open end of the cystoscope, the tube being connected to a source of electrical power by electrically conductive wires making contact with the opposite end thereof.

5 In another form the suction tube is formed from spirally wound wires coated with polytetrafluoroethylene (PTFE), the electrode tip being formed at an uncoated end of the tube, e.g. at the junction of the wires. A single double wound wire may, of course, be used in
10 place of two wires.

A specimen collection vessel may be connected between the end of the tubing and the suction means. The specimen vessel may be in the form of an elongated cylindrical body separable into two portions, the upper
15 portion including an inlet pipe for connection with the said tubing and means for adjusting the suction applied to the tubing and the lower portion including an outlet pipe for connection with the suction means and containing a replaceable filter in which the specimen is
20 collected. The suction adjustment means may be a finger hole formed in the side of the said upper portion or at the end of a pipe communicating therewith.

WO 90/03152

PCT/GB89/01124

5

In one embodiment of the invention a double channel endoscope is employed in which the two channels extending along only a short length of the endoscope before merging into a single channel, the flexible translucent suction tube passes through one channel and the electrode wires, which are not embedded in the tube, through the second channel, where the two channels merge into a single channel the electrode wires then run parallel and adjacent the tubing and are secured to the tubing near the open end in order to maintain the spatial relationship between the electrode tip and tube opening. In another embodiment of the present invention the diathermy tube is a rigid instrument that may be employed in co-operation with advancing mechanism of a urethrotome or the retracting mechanism of a resectoscope. In this apparatus, a rigid insulated metal combined suction and diathermy tube is used, the operative exposed electrode of the mechanism being the distal circumference of the tube or, alternatively, a lateral window formed in the tube wall.

WO 90/03152

PCT/GB89/01124

6

The invention will now be more fully described with reference to the accompanying drawings in which:

- Figure 1 - is a side view of a diathermy tube for use in the invention.
- 5 Figure 1a - is a cross section through A-A of Figure 1.
- Figure 1b - is a perspective view of a fragment of the apparatus Figure 1 in the direction X:
- 10 Figure 2 - is a perspective view of a fragment of an alternative form of diathermy tube for use with the present invention.
- Figure 2b - is an end view of the embodiment Figure 2 in the direction Y.
- 15 Figure 3 - is a side view of a third form of diathermy tube for use with the present invention,
- Figure 4 - is a side view of a fourth form of diathermy tube for use with the
- 20 present invention,
- Figure 5 - is a diagrammatic section through a specimen vessel for use with the present invention.

WO 90/03152

PCT/GB89/01124

7.

Figure 6 - is a diagrammatic illustration of one embodiment of the present invention,

Figure 7 - is an illustration of the operative end of the device of Figure 6,

5 Figure 8 - is an illustration of the other end of the device of Figure 6, and

Figure 9 - is a diagrammatic illustration of another embodiment of the present invention.

10 The diathermy tube of Figure 1 comprises a translucent flexible plastics tube 2 having an end 3 adapted for connection to a suitable suction apparatus, and an open end 4.

Twin electrode wires 5, have ends 6 connected to a
15 diathermy apparatus and extend lengthwise of, and are embedded in, the walls of the tube at opposite ends of a diameter thereof. An exposed tip of the electrode 7 extends beyond the open end of the tube and is in the form of a circular wire ring spaced from end 4 of tube
20 2. In the diathermy tube of Figure 2 the exposed end 8 of the electrode wires 5 is in the form of a semi-circular wire ring adjacent to end 4 of tube 2.

Suction through the diathermy tube is controlled by an aperture, which may be partially or fully closed by

WO 90/03152

PCT/GB89/01124

8.

an operative's finger, formed at the end of the tube adjacent the connection to the suction source or at a point in the means connecting the tube to the said source, e.g. in a specimen collection vessel.

5 In the diathermy tube of Figure 3 the opening 9 in tube 2 is formed in the side wall thereof adjacent to a closed end and the exposed tip of electrode 10 is in a form of a circular wire located within the circumference of the opening.

10 In Figure 4 a diathermy tube, generally indicated at 60 consists of a hollow plastics suction tube 61 having a removable diathermy electric tip 62 connected to a source of electrical power by leads 63 and connector 64. The non-operative end of the tube is connected to
15 a suction device via tube 65 and includes a finger hole 66 to control the degree of suction applied to tube 61. The connector 64 and lead 63 are passed retrogradely through the endoscope from the operative end so that the connector 64 can be connected to a source of electrical
20 power at the other end. The suction tube 61 is then passed down through the endoscope and the electrode tip inserted over it's end, the tip being a press fit over the end of the tube 61.

WO 90/03152

PCT/GB89/01124

9.

A suitable specimen collecting vessel is illustrated in Figure 5. The vessel, generally indicated at 20, comprises two portions 21 and 22 in screw-threaded engagement. Portion 22 contains a pipe 23
5 for attachment to a suitable suction means such as a vacuum pump and further includes a replaceable specimen filter 24 on which tumour portions may be collected. Portion 21 includes a pipe 25 for attachment to the end 3 of tube 2 and further includes a finger hole at 26
10 enabling the vacuum applied through end 23 to be manually adjusted.

A complete apparatus of invention is illustrated in Figures 6, 7 and 8.

A hollow diathermy suction tube 31 having end
15 portions 32 and 33 extends through an endoscope sheath 40 having an open operative end 41 and a closed end 42. Tube 31 consists of an inner chemically inert electrically conducting tube 34, such as stainless steel, covered with an insulating sheath 35 formed of
20 insulating plastics material, such as PTFE, except for end portion 32 which is left bare and which provides the cutting or coagulating electrode tip 34a. End 33 of tube 31 is slidably supported in a bush member 36, which acts to close end 42 of endoscope sheath 40, in a fluid

WO 90/03152

PCT/GB89/01124

10

tight manner. End 33 is releasably secured to the hollow arm 38 of a hand piece 37 to make electrical contact with lead 39 of a diathermy unit (not shown). Hand piece 37 is, in turn, slidably supported on a

5 tubular member 43 secured through bush 36 and extending rearwardly therefrom. Hollow arm 38 of hand piece 37 is attached to a tube 50 communicating with a suction device via an optional specimen collection vessel (not shown) and contains an aperture 38a open to the atmosphere and

10 positioned to permit it to be fully or partially closed by a finger of a user. A thumb plate 45 is provided at the end of 43 tubular support 43. A telescope 46 extends from the open end 42 of the endoscope tube 40 through bush 36 and tubular member 43 and is provided with a

15 light source 47 and an eye piece 48. A washer 49 is located at the end of the telescope 46 adjacent the end of tubular member 43 to make fluid tight contact therewith to prevent fluid seeping through and out of member 43. An irrigation fluid inlet 51 and tap 52

20 communicates with end 42 of endoscope 40 forward of bush 36. A spring member 53 is positioned between thumb plate 45 and hand piece 37 to normally urge the hand piece and therefore the diathermy tube 31 fully forward.

WO 90/03152

PCT/GB89/01124

1.1

When in use the diathermy tube 31 is initially retracted within the endoscope tube 40 by the user applying pressure between the thumb plate 45 and the hand piece 37 and compressing spring 53. The endoscope 40 is then directed into the body organ from which a tumour, for example, is to be removed. The degree of suction applied at the operative end of the diathermy tube is controlled by finger pressure on aperture 38a. The position of the tumour is observed through the telescope 46 and the diathermy tube allowed to move forward under the influence of spring 53. Power from the diathermy unit is switched on and a portion of the tumour cut away by the heated end 32 of the diathermy tube and the severed tissue immediately removed by suction through the open end of the diathermy tube and pipe 50 to a waste collection means. Irrigation fluid is caused to pass into the organ via the tube 51 and endoscope 40 and is sucked away together with blood and severed tissue through the open end of the diathermy tube and through pipe 50 to a waste collection means.

In a simplified form of the apparatus described with reference to Figures 6, 7 and 8 and illustrated in Figure 9, in which like parts have like references, handle 37 is omitted and replaced by end 33 of tube 31

WO 90/03152

PCT/GB89/01124

12

which is bent through 90° to provide an arm 54. A
finger aperture 55 is provided in arm 54 to control the
degree of suction through the tube. Connection to a
diathermy device (or other source of electrical power) is
5 achieved via leads 58 secured via a suitable plug means
to arm 54. Movement of the diathermy tube 31 up and down
the cystoscope is controlled by the user holding the arm
54.

WO 90/03152

PCT/GB89/01124

13

CLAIMS

1. An apparatus for use in the removal of tumours from hollow body organs accessible to an endoscope comprising, in combination, an endoscope (40) having a closed end (42) through which the telescope (48) passes and
5 adjacent to which there is provided an irrigation fluid inlet means, an open operative end (41), and a diathermy suction tube (2, 31, 61) extending through the closed end (42) of the said endoscope to the open end (41) and including an operative end (4, 9, 32) having an exposed
10 electrode tip (7, 8, 10, 34a, 62) portion adjacent to an opening in or at the said operative end of the tube, the said electrode (7, 8, 10, 34a, 62) being connected (5, 39, 56, 63) to a source of electrical power and the other end of the suction tube (2, 31, 62) connected to a
15 vacuum source (50, 65).
2. An apparatus according to claim 1 wherein the source of electrical power is a diathermy machine.
3. An apparatus according to claim 1 or 2 wherein means (38a, 55, 66) are provided adjacent the other end of the
20 diathermy (31, 61) tube to control the degree of suction applied to the said tube.

WO 90/03152

PCT/GB89/01124

14

4. An apparatus according to claim 1, 2 or 3 wherein the diathermy suction tube (2, 61) is formed from flexible translucent plastics material and the said diathermy electrode tip (7, 8) is formed of electrically
5 conductive resistance wire connected to the source of electrical power by at least one electrically conductive wire (5) located in the wall of the said tube.
5. An apparatus according to claim 4 wherein the electrode tip (7, 8) is formed at the end of two wires
10 (5) that are located adjacent to the wall of the tube.
6. An apparatus according to claim 5 wherein the wires (5) are embedded in the wall of the tube.
7. An apparatus according to claim 4 wherein the electrode tip (62) is releasably attached to the
15 operative end of the suction tube (61).
8. An apparatus according to claim 4 wherein the tube comprises spirally wound electrically conductive wires joined at one end to form an electrode tip and coated with an insulating plastics material from a point
20 adjacent, but not including, the said tip.
9. An apparatus according to claim 1, 2 or 3 wherein the diathermy suction tube (31) is formed from an electrically conductive metallic tube (34) coated with an

WO 90/03152

PCT/GB89/01124

15

insulating material (35), the operative tip portion (32) of tube being left bare to provide a diathermy electrode (34a), the said tip portion (32) extending beyond the open end of the endoscope, the tube (34) being connected
5 to a source of electrical power by electrically conductive wires (39, 56) making contact with the opposite end thereof.

10. An apparatus according to any one of the preceeding claims wherein the diathermy tube (2, 31, 61) is
10 retractable along the endoscope whereby the operative electrode tip (7, 8, 10, 34a, 62) may be withdrawn within the endoscope.

11. An apparatus according to claim 10 as dependant upon claim 9 wherein the diathermy tube (31) extends
15 slidably through the closed end (42) of the endoscope and the non-operative end (33) includes a handle (37) supported on means (43) extending coaxially of the endoscope, said support means (43) including at the opposite end thereof a stop means (44), resilient means
20 (53) being positioned between the said handle (37) and the stop means (44) to normally urge the diathermy tube (31) into its forward operative position.

WO 90/03152

PCT/GB89/01124

16

12. An apparatus according to claim 11 wherein the resilient means is a spring (53).

13. An apparatus according to claim 11 or 12 wherein a portion (38) of the said handle (37) is hollow, one end
5 communicating with the diathermy tube (31) and the other end with the said suction means (50).

14. An apparatus according to claim 13 wherein the means to control the degree of suction comprises an aperture (38a) formed in the said handle (37) normally
10 open to the atmosphere and communicating with the hollow portion (38) thereof.

15. An apparatus according to any one claims 11 - 14 wherein the said means (43) extending from the endoscope is tubular and the telescope (46) extends through the
15 said means and into the endoscope.

16. An apparatus according to claim 10 as dependant upon claim 9 wherein the diathermy tube (31) extends slidably through the closed end of the endoscope and the non-operative end (33) thereof extending outwardly of
20 the endoscope is bent through an angle to provide an arm (54) whereby the diathermy tube (31) may be moved up or down the endoscope.

WO 90/03152

PCT/GB89/01124

17

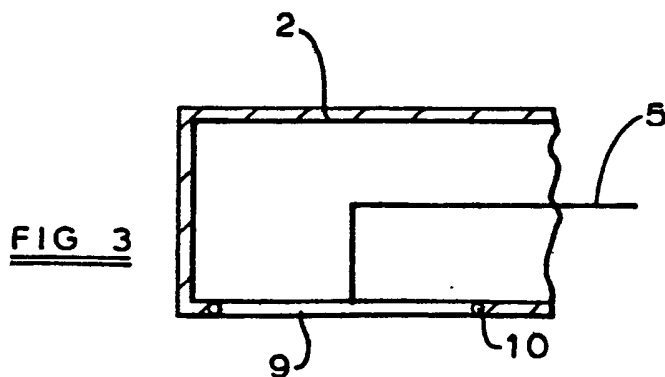
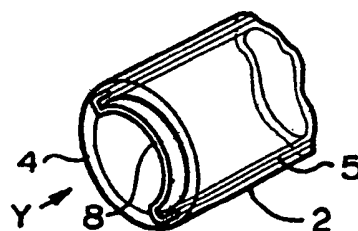
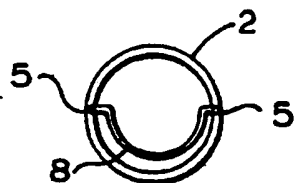
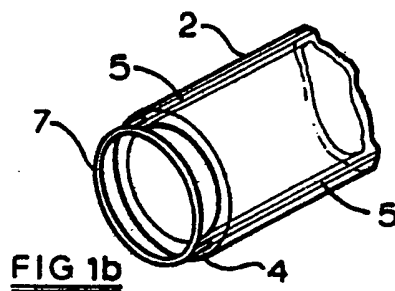
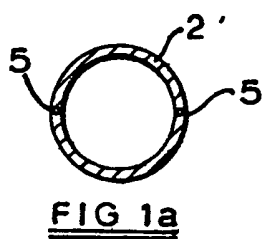
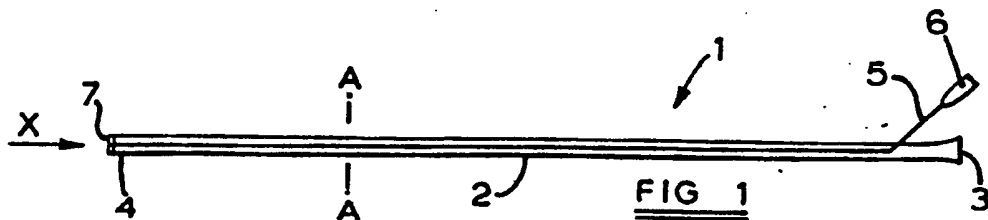
17. An apparatus according to any one of the preceeding claims wherein a specimen collecting vessel (20) is positioned between the diathermy tube and the suction means.

5 18. An apparatus according to claim 17 wherein the specimen collecting vessel (20) includes a replacable filter (24) for the collection of tissue samples.

WO 90/03152

PCT/GB89/01124

1 / 5

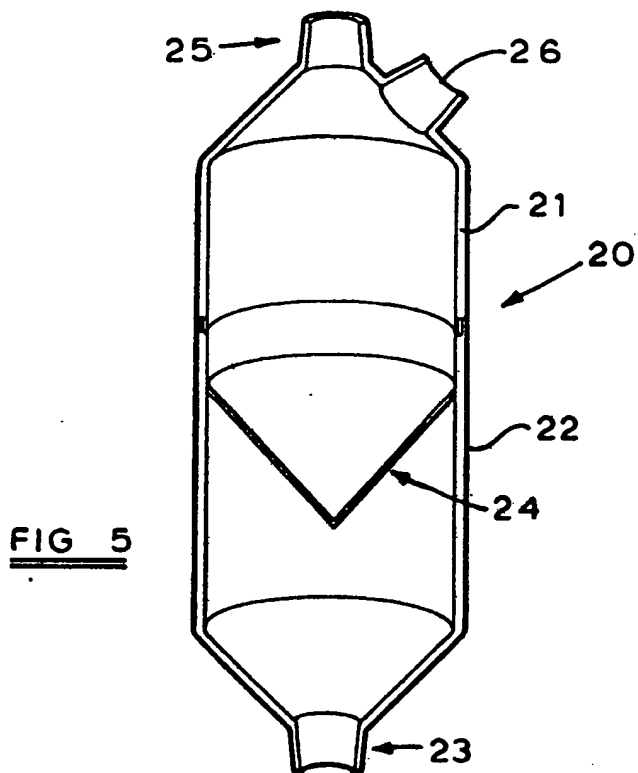
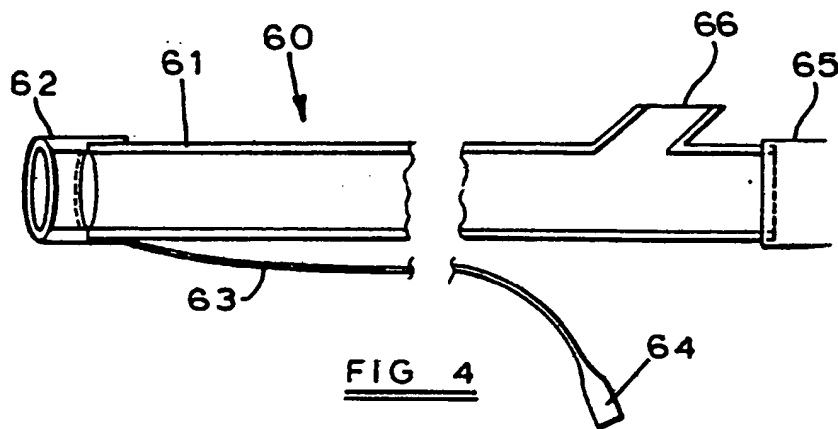


SUBSTITUTE SHEET

WO 90/03152

PCT/GB89/01124

2 / 5



SUBSTITUTE SHEET

WO 90/03152

PCT/GB89/01124

3 / 5

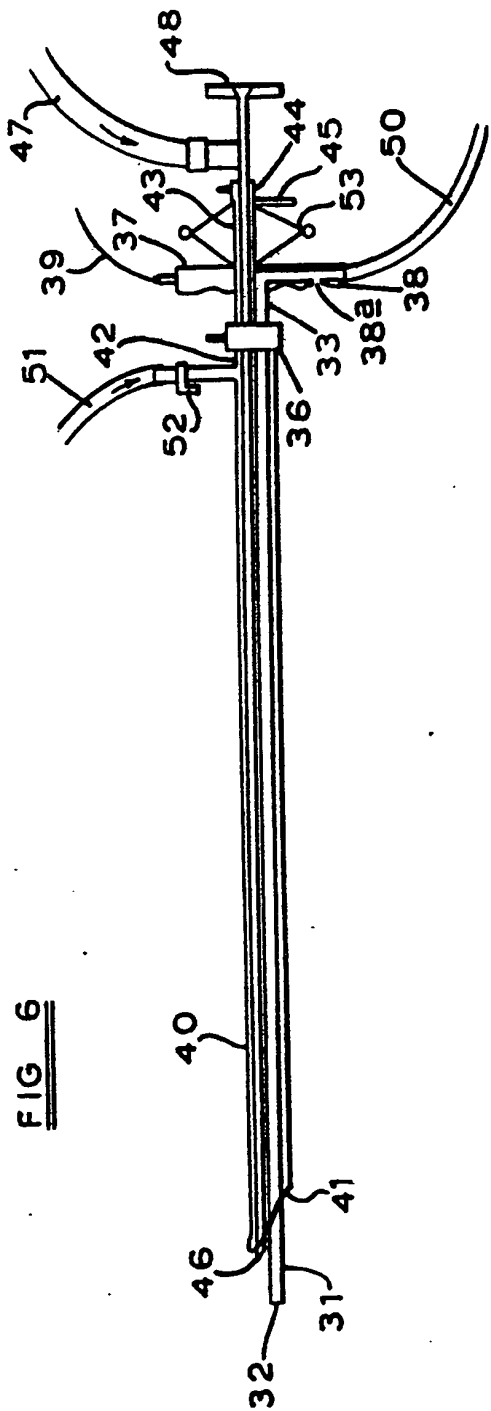
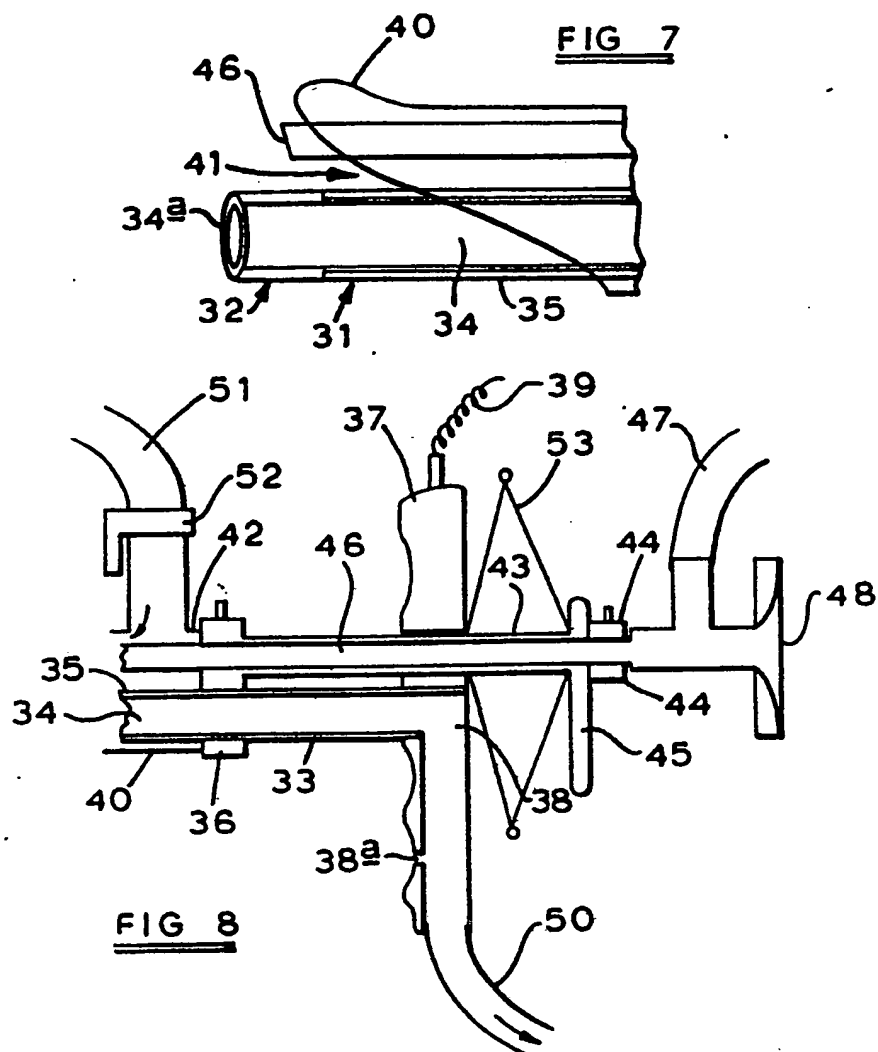


FIG 6

WO 90/03152

PCT/GB89/01124

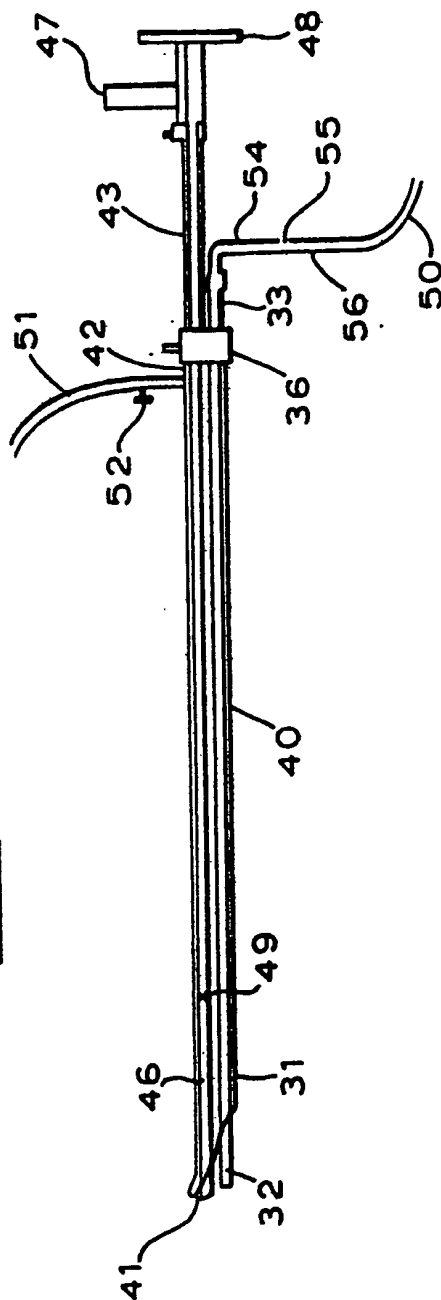
4/5



SUBSTITUTE SHEET

5/5

FIG 9



SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International Application No. PCT/GB 89/01124

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ¹		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁵ : A 61 B 17/39		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁵	A 61 B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	GB, A, 502607 (G. WOLF GMBH) 20 April 1939, see page 2, lines 17-83; figures	1
A	DE, A, 3543594 (OLYMPUS OPTICAL) 10 July 1986, see page 6, line 13 - page 7, line 3; figures 1,2	1
A	DE, A, 3313325 (K. KORTH) 18 October 1984, see page 7, line 15 - page 8, line 15; page 10, lines 20-22; figures	1
A	DE, B, 2324415 (AESCULAP-WERKE AG) 24 October 1974	1
A	US, A 4682596 (T. BALES et al.) 28 July 1987	1
A	US, A, 4060086 (K. STORZ) 29 November 1977	1
A	WO, A, 84/03829 (L. FORINTOS) 11 October 1984	1,3

<p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"A" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
25th January 1990	22. 02. 90	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	T.K. WILLIS	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

GB 8901124
SA 31385

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 09/02/90. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB-A- 502607		None	
DE-A- 3543594	10-07-86	JP-A- 61257639 US-A- 4724836	15-11-86 16-02-88
DE-A- 3313325	18-10-84	JP-A- 60034436	22-02-85
DE-B- 2324415	24-10-74	GB-A- 1449081 JP-A- 50042687 US-A- 3902494	08-09-76 17-04-75 02-09-75
US-A- 4682596	28-07-87	None	
US-A- 4060086	29-11-77	None	
WO-A- 8403829	11-10-84	CH-A- 665948 DE-T- 3490139 EP-A- 0138939 GB-A, B 2146536 JP-T- 60500899 NL-T- 8420077 SE-A- 8405986 US-A- 4686981	30-06-88 04-04-85 02-05-85 24-04-85 20-06-85 01-02-85 27-11-84 18-08-87

EP FORM P001

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)